## II. Remarks

### A. Status of the Claims

Claims 1-9, 29, 30, 41, 54 and 62-69 have been amended without prejudice or admission.

Applicants submit that support for the amendments to claims 1-9, 29, 30, 41, 54, 62, and 64 can be found, e.g., on page 67, line 5, to page 68, line 20, and page 14, line 37, of the original specification; and that support for the amendments to claims 63, 65, 66 and 67-69 can be found, e.g., on page 66, lines 13-17, of the original specification.

Claims 13, 14, 16, and 18 have been cancelled without prejudice or admission.

Claim 60 was previously cancelled without prejudice or admission.

Claims 1-59 and 61-73 are pending.

Applicants respectfully submit that no new matter has been added by virtue of the present amendments.

### B. Claim objections

Claim 66 was objected to for containing a typographical error- the term "is" was recited twice.

Claim 66 has been amended to delete the duplicate occurrence of the term "is."

Withdrawal of the objection is respectfully requested.

### C. Claim Rejectrions 35 U.S.C. § 112

Claims 1-9, 41 and 54 were rejected under 35 U.S.C. § 112, first paragraph. The Examiner stated the claim limitation 'wherein an amount of the antagonist released from the dosage form which has been administered intact is insufficient to produce a physiological effect of the antagonist in a human patient' introduces new matter into the claims." *Office Action, page 3.*

The rejection is respectfully traversed.

Claims 1-9, 41 and 54 has been amended to remove the objected term.

Withdrawal of the rejection is respectfully requested.

### D. Claim Rejections 35 U.S.C. § 103

#### 1. U.S. Patent No. 6,277,384 to Kaiko et al.

Claims 1-59 and 61-73 have been rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 6,277,384 to Kaiko et al. ("the Kaiko reference").

The rejection is respectfully traversed.

In an effort to advance prosecution, independent claims 1-9, 41 and 54 have been amended to recite that an amount of the antagonist "released at 1 and 2 hours from the dosage form which has been administered intact is undetectable by High Performance Liquid Chromatography, and that less than 15% by weight of the opioid antagonist is released within 36 hours after the administration of the intact dosage form, based on an in-vitro dissolution of the intact dosage form in a dissolution bath."

Applicants respectfully submit that the Kaiko reference does not provide a reason for a skilled person to formulate sequestered opioid antagonist particles consisting of an opioid antagonist, a sequestering material and one or more additional pharmaceutically acceptable excipients, wherein the sequestering material separates the antagonist from the agonist and substantially prevents the release of the antagonist from the dosage form which has been administered intact such that an amount of the antagonist released at 1 and 2 hours from the dosage form which has been administered intact is undetectable by High Performance Liquid Chromatography, and less than 15% by weight of the opioid antagonist is released within 36 hours after the administration of the intact dosage form, as recited in independent claims 1-9, 41 and 54.

With further regard to claim 63, Applicants respectfully submit that the Kaiko publication does not provide a reason for a skilled person to formulate an oral dosage form such that "an amount of the antagonist released from the dosage form which has been administered intact is insufficient to produce an antagonistic effect of the antagonist."

In response to the Examiner's statement on page 8 of the Office Action that "the term 'sequestered', even as defined by Applicant's specification, merely requires that the formulation at some point in time be non-releasable," Applicants respectfully note that independent claims 1-9, 41 and 54 have been amended to recite that the opioid antagonist is sequestered "such that an amount of the antagonist released at 1 and 2 hours from the dosage form which has been administered intact is **undetectable** by High Performance Liquid Chromatography."

For these reasons, and the reasons presented in the response filed on April 10, 2009, herein incorporated by reference, withdrawal of the rejection is respectfully requested.

## III. Conclusion

An early and favorable action on the merits is earnestly solicited. According to currently recommended Patent Office policy the Examiner is requested to contact the undersigned by telephone in the event that a telephonic interview will advance the prosecution of this application.

Respectfully submitted,
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